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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,561	11/07/2001	Guo-Bin Wang	32286-232713	3657

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EXAMINER	
BRUENJES, CHRISTOPHER P	
ART UNIT	PAPER NUMBER
1794	
MAIL DATE	DELIVERY MODE
11/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/035,561	WANG ET AL.	
	Examiner	Art Unit	
	Christopher P. Bruenjes	1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *64-73,76-84,87-95 and 98-111* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *64-73,76-84,87-95 and 98-111* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 12, 2007 has been entered.

WITHDRAWN REJECTIONS

2. The 35 U.S.C. 102 rejections of claims 64-70 and 72-109 as anticipated by Michal et al of record in the Office Action mailed August 20, 2007, Pages 2-7 Paragraph 3, have been withdrawn due to Applicant's amendments in the Paper filed October 29, 2007.

3. The 35 U.S.C. 103 rejection of claim 71 over Michal et al in view of Goldberg et al of record in the Office Action mailed August 20, 2007, Pages 8-9 Paragraph 6, have been withdrawn due to Applicant's amendments in the Paper filed October 29, 2007.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 64-66, 68, 71-78, 80, 83-84, 87-89, 92, 94-95 and 111 are rejected under 35 U.S.C. 102(b) as being anticipated by Goldberg et al (USPN 5,804,263).

Regarding claims 64, 76, 83, 87 and 111, Goldberg et al anticipate a medical device comprising a non-layered insertable medical instrument formed from polymers or copolymers selected form the group consisting of polyurethane, polyvinylchloride and silicon, and having at least one lumen and a surface (col.9, l.29-44). A plurality of monomer molecules are directly graft polymerized on at least one of the surfaces of the substrate, forming a coating thereon (col.8, l.25-65). The coating is a polymer or copolymer or a derivative of said polymer or copolymer formed from a monomer or derivative thereof selected from the group consisting of an acrylamide, N,N-dimethylacrylamide, hydroxyethylmethacrylate, vinylpyridines and mixtures thereof (col.7, l.55-60 and col.8, l.7-18).

Regarding claims 65-66, 77-78, and 88-89, the medical device is a catheter, guide wire or medical instrument (col.8, l.57-65).

Regarding claims 68, 80, and 92, the coating is a hydrophilic agent made of acrylamide or N,N-dimethylacrylamide so inherently absorbs large quantities of water to provide moisture absorption or of lubricity.

Regarding claim 71, the instrument is a silicon polymer (col.9, l.29-35).

Regarding claim 72, the instrument is a polyurethane (col.9, l.39-44).

Regarding claims 73, 84, 92 and 94-95, the entire surface of the interior surface, exterior surface or both of the substrate are coated.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 67, 69-70, 79, 81-82, 90-91, 93, and 98-110 rejected under 35 U.S.C. 103(a) as being unpatentable over Goldberg et al as applied to claims 64, 76, and 87 in view of Michal et al (USPN 6,287,285).

Regarding claims 98-100, Goldberg et al teach all that is claimed in claims 64, 76, and 87 as shown above, but fail to teach that the instrument further comprises at least one cross-linking agent or at least one monomer substituted with functional groups. However, Michal et al teach that when forming graft coated catheters containing the same coating compositions as claimed by Applicant and presented in Goldberg et al, the coating can be applied directly to the catheter (col.5, l.9-15). Michal et al also teach that the coating can contain a linking agent that is either incorporated in the coating or bonded to the instrument prior to applying the hydrophilic agent or coating to improve the binding between the instrument and the therapeutic or hydrophilic coating

(col.2, l.55-67). Therefore, it would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to add a cross-linking agent or at least one monomer substituted with functional groups to the coating of Goldberg et al in order to improve the bond between the coating and the instrument.

Regarding claims 67, 79, and 90, in the embodiment in which the linking agent is applied separately to the instrument the linking agent forms an additional polymeric layer.

Regarding claims 69, 81, and 93, Michal et al teach that the linking agent is used to bond physiologically or pharmacologically active agents (col.4, l.1-9).

Regarding claims 70 and 82, the coating comprises a drug depot permitting the delivery of drugs form the graft polymer coating (col.4, l.10-65).

Regarding claim 91, the coating in Goldberg et al includes acrylics.

Regarding claims 101-105, Michal et al teach the at least one cross-linking agent is divinylbenzene (col.3, l.1-5 and 49-64) and the monomer substituted with functional groups include functional groups such as amine, carboxylic acid or hydroxyl (col.9, l.46-56).

Regarding claims 106-110, Michal et al teach the drugs include drugs such as heparin or paclitaxel which are antithrombogenic or anticancer agents (col.4, l.1-9).

Response to Arguments

9. Applicant's arguments with respect to claims 64-109 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher P. Bruenjes whose telephone number is 571-272-1489. The examiner can normally be reached on Monday thru Friday from 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on 571-272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christopher P Bruenjes
Examiner
Art Unit 1794

CPB
November 7, 2007